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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,766	03/22/2004	Jacob Fraden		2415

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03/27/2008

EXAMINER

BERHANU, ETSUB D

ART UNIT	PAPER NUMBER
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3768

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/806,766	Applicant(s) FRADEN, JACOB	
	Examiner ETSUB D. BERHANU	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

2. Claims 1-5 are objected to because of the following informalities: the term - - a - - should be inserted between the terms "wherein" and "distal" in line 3 of claim 1; the term - - a - - should be inserted between the terms "and" and "proximal" in line 4 of claim 1; the term - - said - - should be inserted between the terms "from" and "first" in line 3 of claim 2; the term "computer" in line 3 of claim 2 should be amended to read - - computing - -; the term - - a - - should be inserted between the terms "for" and "wavelength" in line 3 of claim 3; the term - - a - - should be inserted between the terms "monitoring" and "patient's" in line 1 of claims 4 and 5; the term - - the - - should be inserted between the terms "comprising" and "steps" in line 3 of claims 4 and 5; the term - - a - - should be inserted between the terms "Attaching" and "temperature" in line 4 of claim 4; the term - - a - - should be inserted between the terms "Measuring" and "temperature" in lines 9 and 10 of claim 4; the term - - a - - should be inserted between the terms "minimize" and "temperature" in line 11 of claim 4; the term - - a - - should be inserted between the terms "Computing" and "level" in line 13 of claim 4; the term "to" in line 4 of claim 5 should be replaced with the term "into"; the term - - a - - should be inserted between the terms "Measuring" and "surface" in line 8 of claim 5; the term - - a - - should be inserted between the terms "Measuring" and "temperature" in line 9 of claim 5; the term - - a - - should be inserted between the terms "minimize" and

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“temperature” in line 10 of claim 5; the term - - a - - should be inserted between the terms “Computing” and “level” in line 12 of claim 5. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites the limitation “said temperature sensor” in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 improperly recites human tissue as part of the claimed invention in the phrase “said housing extension is inserted into the patient ear”. It is suggested that Applicant amend the claim to include the phrase "adapted to be inserted" or "capable of being inserted" in order to remove human tissue as part of the claimed invention.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulze et al.'692 (USPN 5,673,692).

Figures 2 and 10 of Schulze et al.'692 disclose a system for detecting photo-plethysmographic signals from a patient ear canal, the system comprising: a sensor's housing (col. 7, lines 7-12); a first and second light emitting source operating at different wavelengths and a light detector (col. 4, lines 3-8), wherein a distal end of a housing extension is capable of being inserted into the patient's ear and a proximal side of the extension is optically coupled to the light emitting sources and light detector (see description of Figures 2 and 10). Schulze et al.'692 also discloses that the system comprises a processor for computing arterial blood oxygen saturation levels (col. 4, lines 45-49). Schulze et al.'692 further discloses a temperature sensor on the distal portion of the housing, wherein the temperature sensor is configured to measure a patient's core body temperature (col. 3, lines 37-45). Schulze et al.'692 discloses that the light emitting sources and temperature sensor are placed within an ear plug to be placed within the patient ear canal (col. 4, lines 9-15).

9. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Schulze et al.'852 (USPN 6,556,852).

Schulze et al.'852 discloses a system for detecting photo-plethysmographic signals from a patient ear canal, the system comprising: a sensor's housing (the earmold probe discussed in col. 8, lines 48-51); a first and second light emitting source operating at different wavelengths and a light detector (col. 4, lines 3-8), wherein a distal end of a transparent housing extension (earmold insert) is capable of being inserted into the patient's ear and a proximal side of the extension is optically coupled to the light emitting

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sources and light detector (see description of Figure 1 and col. 8, lines 51-53). Schulze et al.'852 also discloses that the system comprises a processor for computing arterial blood oxygen saturation levels (see description of Figure 5 and col. 2, lines 49-54).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al.'692, further in view of Fraden et al.'405 (USPN 6,773,405).

Schulze et al.'692 discloses a method for monitoring a patient's arterial blood oxygenation and core body temperature by an ear probe consisting of a housing, ear plug, two light emitting devices, one light detecting device and a temperature detector (see paragraph 8 above), the method comprising the steps of: attaching a temperature sensor to a flexible ear plug, inserting the ear plug into the patient's ear canal, alternatively transmitting two wavelengths of light to the ear canal and measuring the reflected light, measuring a temperature of the ear plug with the temperature sensor, computing a level of blood oxygenation from signals received from the light detecting device and computing the patient core temperature (col. 3, lines 37-45 and col. 4, line 9 – col. 5, line 24). Schulze et al.'692 discloses all the elements of the current invention, as discussed above, except for the method comprising measuring a temperature of the ear probe, generating heat with a heater to minimize a temperature difference and computing a patient core temperature from signals received from temperature sensors. Fraden et al.'405 teaches compensating for a heat lost from the ear canal to the environment with the use of an external temperature sensor and heating element on an ear probe by measuring a temperature of the ear probe with

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the external temperature sensor and generating heat with a heater to minimize a temperature difference between the internally measured temperature and the externally measured temperature in order to negate a temperature gradient across the plug and produce a patient core body temperature measurement with high accuracy (see ABSTRACT and col. 2, lines 8-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Schulze et al.'692 to include measuring a temperature of the ear probe with a temperature detector and generating heat by a heater to minimize a temperature difference, as taught by Fraden et al.'405, since it would produce more accurate patient core body temperature measurements.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Beaumont'034 (US Pub No. 2005/0177034) discloses an ear canal sensing device capable of non-invasively monitoring physiological factors of a patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/

Primary Examiner, Art Unit 3768